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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/998,880

10/31/2001

E. Skott Greenhalgh

24426-A USA

7282

7590

08/10/2004

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EXAMINER

NAFF, DAVID M

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

844.

## Office Action Summary

**Application No.**

09/998,880

**Applicant(s)**

GREENHALGH ET AL.

**Examiner**

David M. Naff

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/4 &amp; 6/25/02</u> . | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

In a response of 7/19/04 to a restriction requirement of 6/15/04, applicants amended the specification, elected Group I claims 1-19 without traverse, canceled Group III claims 22 and 23, and withdrew  
5 Group II claims 20 and 21 pending a finding of allowable subject matter in claims 1-19 and the possibility of rejoinder as process of making and product made.

Claims 20 and 21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention,  
10 there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/19/04.

### *Specification*

The disclosure is objected to because of the following informalities: at page 9, line 8, "follows" should be -- follow --.

15 Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

20 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

25 Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for large interstices having a large size relative to cells being cultivated such that cultivated cells do not bridge the interstices and grow across the

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support substrate as disclosed in the specification (page 8, lines 17-23), and the small interstices are of a size of about 60-80 microns as in claim 4 and disclosed in the specification ((page 11, line 13), does not reasonably provide enablement for other sizes within the  
5 scope of "relatively large" and "relatively small". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims must be commensurate in scope with the specification.

10 The specification supports the supported lattice functioning as disclosed only when the large and small interstices have sizes set forth above. It would be speculation and unpredictable as to other sizes that will provide the results disclosed in the specification.

***Claim Rejections - 35 USC § 112***

15 Claims 13 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a buckled configuration as in line 4 of claim 13 when the flexible filamentary members are locked to provide the buckled configuration as required by claim 15, does not reasonably provide enablement for a  
20 buckled configuration when the filamentary members are not locked as in claim 15. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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If the filamentary members are not locked as in claim 15 when obtaining a buckled configuration, the buckled configuration will not be maintained after buckling occurs. The specification discloses no way of maintaining the buckled configuration other than as required by claim 15.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C.

112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 and where recited in other claims "relatively coarse", "relatively large", "relatively fine" and "relatively small" are uncertain as to meaning and scope since being "relative" is subjective and depends on what is being compared with.

Claim 11 is confusing by being unclear as to whether the large interstices or the small interstices have the size of "between about 120 microns and about 150 microns" contained by the first tube and "between about 60 microns and about 80 microns" contained by the second tube. The specification (page 11, line 13) supports only the small interstices having a size of about 60-80 microns. Therefore,

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the 120-150 microns would have to be size of the large interstices or otherwise the relatively small interstices will not be smaller than the relatively large interstices. Claim 11 should be accordingly amended to require the small interstices to be 60-80 microns and the large interstices to be 120-150 microns.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-9, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Thompson (5,718,159).

The claims are drawn to a supported lattice for cultivating cells to form tissue containing the support substrate and a cell cultivation lattice. The support substrate is formed of resilient filamentary members interlaced together to form relatively large interstices. The lattice is formed of flexible filamentary members interlaced with each other and the resilient filamentary members to form relatively small interstices.

Thompson discloses implantable prosthesis including stents and grafts intended for intraluminal fixation (col 1, lines 4-7). The prosthesis can be formed by interbraiding multiple structural strands with multiple textile strands (col 7, lines 14-20). The textile

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stands (col 7, lines 40-60) are preferably multifilament yarns, but can be monofilaments. The textile strands are 10-400 denier and can be made of polypropylene or polyethylene. The textile strands form a sheeting or fabric that is microporous. The structural strands can be stainless steel (col 6, line 24) or Elgiloy wire having a diameter of 0.0047 inches (0.12 mm), and braiding is on a mandrel (col 11, lines 48-53). Interstices between adjacent structural strands are occupied by textile sheeting or fabric formed by the textile strands (paragraph bridging cols 7 and 8 and Figures 5 and 6).

The prosthesis of Thompson has a structure as presently claimed and is encompassed by the present claims. The sheet or fabric of the prosthesis is inherently capable of functioning for cultivating cells to form tissue.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art  
5 under 35 U.S.C. 103(a).

Claims 4 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson in view of Vyakarnam et al (6,534,084 B1).

Claim 4 requires the small interstices to be about 60-80 microns, and claim 17 requires the resilient and flexible filamentary members  
10 to comprise bio-absorbable material.

Thompson is described above.

Vyakarnam et al disclose bioabsorbable polymer foams (col 4, line 11) for implanting as a scaffold for cell growth for tissue regeneration. The foam can be a multiplayer tubular structure that  
15 allows regeneration of tissue that mimics the characteristics of blood vessels (col 9, lines 25-30). The structure can contain pores for cell invasion of a size of 80  $\mu\text{m}$  (col 6, line 46) or in a range of 80-120  $\mu\text{m}$  (col 6, lines 28-29), or 60  $\mu\text{m}$  pores or in a range of 60-200  $\mu\text{m}$  (col 16, lines 8-10).

20 It would have been obvious to make the structural and textile strands of Thompson from a bioabsorbable polymer so the prosthesis will absorb into the body as suggested by Vyakarnam et al.

Additionally, it would have been obvious to provide the sheeting or



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fabric between the structural strands of Thompson with a pore size of 60-80  $\mu\text{m}$  as suggested by Vyakarnam et al for cell invasion.

***Claim Rejections - 35 USC § 102***

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being

5 anticipated by Stinson (5,891,191).

The invention is described above.

Stinson discloses structure for a prosthesis including stents and stent grafts containing structural and textile strands essentially as disclosed by Thompson.

10 The prosthesis of Stinson has a structure as presently claimed and is encompassed by the present claims. The sheet or fabric of the prosthesis is inherently capable of functioning for cultivating cells to form tissue.

***Claim Rejections - 35 USC § 103***

15 Claims 5-9, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stinson in view of Thompson.

The claims require the resilient filamentary members to be monofilaments selected from stainless steel, nitinol and elgiloy monofilaments.

20 Thompson discloses that the structural strands can be stainless steel or Elgiloy wire.

It would have been obvious to use stainless steel or Elgiloy wire as the structural strands of stinson as suggested by Thompson.

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***Claim Rejections - 35 USC § 103***

Claims 4 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over stinson in view of Vyakarnam et al for reasons set forth above when rejecting these claims over Thompson in view of

5 Vyakarnam et al.

***Conclusion***

Claims 10-16 are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff  
10 whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this  
15 application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff  
Primary Examiner  
Art Unit 1651

DMN  
8/6/04